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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,361	10/24/2005	Peter K Law	LAW.020.0007.PC	3915
58789 7590 12/13/2007 NDQ&M WATCHSTONE LLP 1300 EYE STREET, NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005			EXAMINER HUGHES, ALICIA R	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,361	Applicant(s) LAW, PETER K	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-16 are pending and the subject of this Office Action.

Claim Rejections - 35 U.S.C. §112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claim 5, as written, is vague and indefinite, because the claim includes reference to "VEGF165", but does not disclose to what VEGF165 refers. When Applicant makes a claim which references a particular for the first time in a claim set, Applicant should write out the full name of the particular to which he refers and accompany that full name with the abbreviation in brackets, if desirous of using an abbreviation of same thereafter.

Claim 5 is rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claim 5, as written, is vague and indefinite, because the claim includes reference to "TGFB", but does not disclose to what TGFB refers. When Applicant makes a claim which references a particular for the first time in a claim set, Applicant should write out the full name of the particular to which he refers and accompany that full name with the abbreviation in brackets, if desirous of using an abbreviation of same thereafter.

Claim 5 is rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claim 5, as written, is vague and indefinite, because the claim includes reference to "NGF", but does

not disclose to what NGF refers. When Applicant makes a claim which references a particular for the first time in a claim set, Applicant should write out the full name of the particular to which he refers and accompany that full name with the abbreviation in brackets, if desirous of using an abbreviation of same thereafter.

Claim 5 is rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claim 7, as written, is vague and indefinite, because the claim includes reference to "high grade body cream." However, nowhere in the disclosure does one find a reference to how high grade body cream is defined. Applicant should make clear his meaning.

Claim Construction

For the purpose of examination herein, claims are assigned their broadest reasonable interpretation. As such, "VEGF165" is construed to mean vascular endothelial growth factor - 165, "TGFB" is construed to mean transforming growth factor beta, and "NGF" is construed to mean nerve growth factor.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,720,963 [hereinafter referred to as "Smith"] in view of U.S. Patent No. 5,919,702 [hereinafter referred to as "Purchio et al"] as evidenced by Cermelli, Silvia, et al., "Extracellular Fatty Acid Binding Protein (Ex-FABP) Modulation by Inflammatory Agents: 'Physiological' Acute Phase Response in Endochondral Bone Formation," *European Journal of Cell Biology*, Vol. 79, pages 155-164 (March 2000).

Smith discloses a method of rejuvenating skin through the process of exfoliation with a 0.5% concentration of RETIN A (trademark) in a simple cream base and as well, a mechanical exfoliation with 5% polyethylene beads suspended in a gel, vigorously applied and rinsed off twice daily (Col. 19, lines 10-15). Smith also teaches that barrier disruption or exfoliation treatments are known in the cosmetic art to be carried out by means of vigorous massage and the use of exfoliative granules (Col. 6, lines 19-24). Smith also teach that water barriers in the skin are control points for skin conditioning and that by "regulating one or more of the skin's growth processes and that by disrupting the water barrier to increase diffusion of moisture through the skin to the ambient air, it is possible to stimulate desirable skin growth processes" (Col. 5, lines 10-15), thereby achieving optimal skin appearance (Col. 5, lines 16-19).

Purchio et al disclose compositions and methods for the production of cartilage tissue (Col. 1, lines 6-8) utilizing pre-chondrocytes and that the same may be utilized for "augmentation of facial or other body features, such as for cosmetic purposes" (Col. 7, lines 15-16; Col. 9, lines 32-38). However, it is well-known in the biological and biochemical arts, that laboratory processes, both *in vivo* and *in vitro*, for ascertaining chondrocytes, myoblasts, and fibroblasts parallel, *see Cermelli*, generally, most particularly the Abstract), making the teachings

in Purchio et al germane to the instantly disclosed application. Also, as noted in Purchio et al, mesenchymal cells, which are known potentiators of multipotential cells, including for example skeletal tissues such as cartilage, bone tendon, ligament, marrow stroma and connective tissue are also contemplated (Col. 3, lines 5-33).

Purchio et al disclose the methods of isolating pre-chondrocytes which develop chondrocytes and mitotically expand in culture, *in vitro*, to autologous chondrocytes, which can be cryopreserved and stored frozen to form banks of cells that can be thawed and utilized, either *in vivo* or *in vitro*, to produce new tissue as needed (Col. 1, lines 5-19; Col. 2, lines 14-29). Purchio et al also disclose that chondrocytes can be obtained from normal mature tissue, too, by for example, digesting articular cartilage into a collagenase solution, followed by mitotic expansion in an *in vitro* culture prior to implantation (Col. 2, lines 32-38) and that upon the mitotic expansion enough to generate a sufficient density, the cells can be autologously, heterologously, allogenicly or xenogenically utilized (Col. 2, lines 19-52).

Purchio et al explicitly discloses the creation of new tissue “prepared from the cells of the invention and [] used to repair, replace or augment cartilage tissue in a subject using any technique of repair, replacement or augmentation known in the art *or to be developed in the future*” (Col. 6, lines 43-46)(Emphasis added).

Purchio et al also disclose that cells of the invention can be either seeded with or coated with one or more bioactive agents or other compounds which can be growth factors (Col. 6, lines 60-65). Growth factors have paracrine or autocrine effects on cell metabolism and can retard or enhance cell division, matrix synthesis and/or degradation (Col. 3, lines 42-45). Most notably, transforming growth factor [“TGF β ”], for example, is known to regulate the growth and

differentiation of multiple cell types (Col. 3, lines 48-50) and to increase the synthesis and secretion of collagen and fibronectin (Col. 4, lines 36-37; please refer generally to Cols. 4 and 5 for the activity of other growth factors).

Purchio et al disclose a cell suspension that can comprise digested cells incubated in vitro in culture medium well-known in the art as commonly established practice, along with human serum, equine serum or bovine serum, antibiotics or antibodies, along with growth factors (Col. 11, lines 26-42), such as TGF β (Col. 13, lines 20-34; see generally Cols. 9-16) and chondroitin-6-sulfate (Col. 18, line 18). Other cell types may also be utilized in the suspension (Col. 16, lines 52-53). The cells may include "but are not limited to, fibroblasts, endothelial cells, pericytes, macrophages, monocytes, plasma cells, mast cells, adipocytes, etc., among others" (Col. 18, lines 57-61).

One of ordinary skill in the art would be motivated to combine Smith and Purchio et al, because they teach overlapping subject matter, cosmetic improvement through natural processes.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to invent a method for refurbishing skin exfoliation followed by the application of a myoblast cell-nutritive solution.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

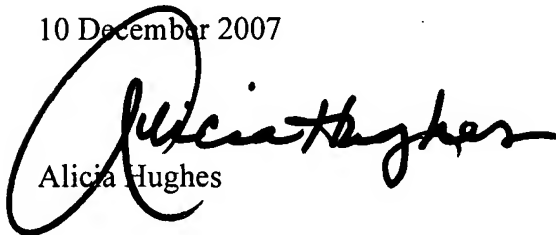
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 December 2007


Alicia Hughes


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER